UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,924	01/13/1998	CHRISTIANE LAUK	P2941WOUS	8634

7590 12/02/2004

SCHUSTER & PARTNER
WIEDERHOLDSTR 10
STUTTGART, 70174
GERMANY

EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/02/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/981,924	LAUK, CHRISTIANE	
	Examiner	Art Unit	
	David A Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 9-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The preliminary amendment of 1/13/98 has been entered. Claims 10-16 are pending and under examination.

The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application-by-application number and filing date is required.

Note alteration of claim 13 in the preliminary amendment.

Claims 9 and 10 are objected to because of the following informalities: In claim 9, step h) would read less awkwardly if -- the comparison of -- were to be inserted after "analyzing". In claim 10 it is believed that "homeophatic" should read as--homeopathic--. Appropriate correction is required.

Claim 13 recites new matter by virtue of reciting new subgenuses of cells. Following original claim 5, the Markush group of claim 13 must read as--normal allergenic cells, normal autogenic cells and normal xenogenic cells--in order to not enter new matter.

Claims 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is completely confusing as to what the goal of the method may be, as to what "activity" of immune cells is being measured, as to how the added components interact, and as to what conclusions are to be drawn from the measurements/ determinations. More particularly, the preamble refers to a "compound" while no

"compound" is recited in any claim step. Is the "compound" the same as the "substrate" or the "pharmaceutical product", or is it something else?

In step c) "changes via cell interactions" is unclear. Does this "change" result from interactions between "immune" and "target" cells; and, if so which of these two cell types is the one which "changes" the structure of the substrate: It is also not clear what kind of "interactions" between the "immune" and "target" cells might be–e.g. do the "immune" cells become activated by the target cells. Do the "target" cells become lysed by the "immune" cells?

In step d) it is not clear what kind of base "activity" is being determined and what product the spectrophotometer is being used to measure. Is the spectrophotometer being used to measure the "change" in the structure of the "substrate" and, if so , is it being used to measure a structural "change" of an intracellular (in which of the two cell types) or of an extracellular product?

In step e) "xenogenic" is unclear. Is this with respect to the "individual organism" or to the "target cells"?

In step F) "reaction activity" is unclear. Is this also conducted with a spectrophotometer to measure whatever product was determined in step d)?

Step h) is unclear as to how the comparing of previous step g) can result in a "tolerance". It is unclear what kind of effect or reaction the "individual organism" is supposed to "tolerate". If the activity of step f) is higher than that of step d), does this indicate a "tolerance" or the opposite thereof?

Likewise, step h) is unclear as to how the comparing of previous step g) can result in "effectiveness". It is unclear what kind of result or reaction is supposed to show "effectiveness" for the "individual organism". If the activity of step f) is higher than that of step d), does this indicate and "effectiveness" or the opposite?

In step i) "undesirable effects" are unclear. Previous step h) has stated nothing absent "undesirable effects" and it is not clear what kind of effect or reaction is "undesirable". Is lack of "tolerance" desirable or "undesirable"? Is "effectiveness" desirable or "undesirable"? If the activity of step f) is higher than that of step d), does this indicate an "undesirable effect" or the opposite?

In step j) "effectiveness" and "tolerance" are unclear for reasons noted supra.

In step j) " possible alternative xenogenic pharmaceutical products" is unclear; are the "first and second products" to be considered "alternative" to each other, or are the "first and second products" to be considered as alternative to as set of additional products that would be listed as the 3rd through Nth?

In claim 10 "homoeopathic active substances" is unclear. What property or effect makes these "active"?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hulsen et al in view of Rohehm et al.

Hulsen et al, as admitted by applicant at specification page 1, show the essential aspects of the instant invention, except that they use radioactive tritium, rather than a "substrate", to measure viability of target cells.

Examiner notes that Hulsen et al obtained immune cells (PBMC) from normal individuals or tumor bearing individuals (page 530, col. 1). These cells were then incubated with each of three xenogenic pharmaceutical products all derived from mistletoe plants (page 530, col. 2). These incubated immune cells are then mixed with target cells, which are k 562 cancer cells (page 530, col. 2). Cytotoxicity of the immune cells against the target K 562 is then measured as an activity.

It is noted that Hulsen et al add the xenogenic pharmaceutical product to the immune cells with target cells. This does not preclude use of this reference, because nothing requires that steps b) and c) of instant claim 9 be conducted sequentially.

Hulsen et al also provide control tests to determine spontaneous release: immune cells are incubated with media alone (p. 530, col. 2-3). These incubated cells correspond to those used in instant step d) to determine a "base activity". Hulsen et al compare the cytotoxic effects of the pharmaceutical upon incubated immune cells and control immune cells by calculating a "percentage of cytotixocity (p. 530 col. 3). Hulsen

et al then use these calculated results to evaluate the effectiveness of each of the pharmaceutical preparations for each of the patients (page 590, col. 3–page 59, col. 1).

As stated supra Hulsen et al use radioactive tritium rather than a substrate to measure the viability of target cells. Motivation to use a substrate, such as a tetrazolium salt, is provided by Rohehm et al. They teach that use of the tetrazolium salt MTT provides the advantage of avoiding the use of radioisotopes (page 257, col. 2). They teach that use of the tetrazolium salt XTT provides the additional advantage of avoiding the need to dissolve the formazan crystals formed as a product of the MTT substrate (page 257, col. 2–page 258, col. 1). The products of the MTT or XTT substrates are read on a spectrophotometer (The microplate readers used by Rohehm et al. at page 259, cols. 1 and 2 provide "spectrometric" readings). One would have thus be fully motivated to use a substrate, such as the MTT or XTT taught by Roehm et al, in lieu of the radioactive tritium used by Hulsen et al.

Hulsen et al and Roehm et al are cited on attached from PTO-892 but are not provided with this action. These references and others were provided by applicant in a disclosure statement, which lacked form PTO–1449. References not relied upon for prior art teachings art not listed on form PTO 892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
November 5, 2004

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644